REMARKS

I. STATUS OF THE CLAIMS

Claims 1-4, 6-8, 10, 11, 14, 15, 17-20, 23, 24, 26-34 are pending in the present application. Claims 4, 19, 23, and 31 have been canceled hereby. Claims 35-46 have been added hereby. In the Office Action dated April 22, 2004, claims 6, 7, 27, 29, 30 and 32 were allowed. Claims 1-4, 8, 10, 11, 14, 15, 17-20, 24, 26, 28, 31, 33 and 34 were rejected. Claim 23 was indicated as being allowable if rewritten as an independent claim.

Claims 1, 20, and 28 have been amended to recite that the body used to form the prosthesis is compressible. Support for this amendment can be found throughout the specification, for example, at page 11, line 20-22 (the prosthesis may be "configured to be compressible, and therefore capable of absorbing compressibility forces applied to the spinal column of the patient"). Thus, no new matter is presented by this amendment.

Claims 8 and 11 have been amended to correct a minor typographical error, inconsistency, or to modify the dependency of the claim.

Claims 26 and 33 have been amended to recite that the body of the prosthesis is formed from a length of biocompatible, compressible, resilient ribbon. Support for this amendment can be found throughout the specification, for example, at page 13, lines 8 through page 14, lines 1-2.

Claim 35 has been added. New claim 35 presents the same subject matter as presented in previously allowed claim 23, written in independent form.

Claim 36 has been added. Claim 36 depends from claim 34 and recites specific materials that may be used in accordance with the present invention. Support for new claim 36 can be found at least at page 15, lines 13-15.

Claims 37-45 have been added. New claims 37-45 are directed to a method of maintaining an intervertebral space between adjacent vertebrae including making an incision in an intervertebral disc and inserting into the interior of the intervertebral disc a biocompatible material. Support for new claims 37-45 can be found at least at page 13, lines 8 through page 14, lines 1-2 of the present application. Thus, no new matter is presented by these claims.

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Claim 46 has been added. Claim 46 is directed to a sheet of biocompatible material for use in intervertebral disc procedures. Support for new claim 42 can be found on at least at page 13, lines 8 through page 14, lines 1-2 of the present application. Thus, no new matter is presented by this claim.

II. CLAIM OBJECTIONS

In the Office Action, claim 23 was objected as being dependent upon a rejected independent claim. As such, claim 23 has been rewritten as independent claim 35 including all the limitations of claim 20, which claim 23 depended from.

III. CLAIM REJECTIONS UNDER 35 U.S.C. §112

In the Office Action, the Examiner rejected claims 1-4, 8, 10, 11, 14, 15, and 17-19 under 35 U.S.C. §112 for allegedly failing to comply with the written description requirement. Specifically, the Examiner asserted that the original disclosure does not adequately support "making the prosthesis of a resilient non-bone material being the only solid material of the body".

Claims 2-4, 8, 10, 11, 14, 15, and 17-18 depend directly or indirectly from claim 1. Claim 19 has been canceled. Without addressing the merits of this rejection, claim 1 has been amended to further clarify Applicant's invention. In light of the present amendment, the rejection under 35 U.S.C. §112 is moot and should be withdrawn.

IV. CLAIM REJECTIONS UNDER 35 U.S.C. §103(A)

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference or combination of references must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); MPEP §2142. It is

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respectfully submitted that the Office Action has failed to set forth a *prima facie* case to support a rejection of the currently pending claims under 35 U.S.C. §103(a), as will be discussed below.

A. Rejection under 35 U.S.C. §103(a) over U.S. Patent No. 4,349,921 to *Kuntz*

In the Office Action, claims 1, 4, 14, 15, 17, 18, 20, 24, 28, 31, and 34 are rejected as being allegedly unpatentable under 35 U.S.C. §103(a) over U.S. Patent No. 4,349,921 to *Kuntz* ("*Kuntz*"). This rejection is respectfully traversed.

The present invention as recited in amended independent claims 1, 20, and 28 is directed to an intervertebral prosthesis that is both resilient *and* compressible. Thus, the present invention is designed to permit some degree of compression to enable flexibility, yet is sufficiently resilient to resist undesirable deformation. *Kuntz* does not teach or suggest a prosthesis that is both resilient *and* compressible. *Kuntz* is directed to an intervertebral disc prosthesis formed from a "substantially rigid" material (*Kuntz*, claim 1). "[I]t is generally preferable to select a material that resists compression or flexing, particularly in the case of a cervical prosthesis." (*Kuntz*, col. 1, lines 63-65). As such, *Kuntz* teaches away from Applicant's invention as set forth in independent claims 1, 20, and 28 and their associated dependent claims.

As regards claim 34, the Office Action did not specifically assert how *Kuntz* renders the claimed subject matter obvious. Applicant has diligently searched *Kuntz* and was unable to find a single reference to delivering to the intervertebral space a substance that, when in the intervertebral space, has a consistency ranging from a semi-solid state to a solid state. As such, *Kuntz* is insufficient to support a rejection of claim 34 under 35 U.S.C. §103(a).

Given that *Kuntz* does not teach or suggest all elements of Applicant's claimed invention, the rejection of claims 1, 4, 14, 15, 17, 18, 20, 24, 28, 31, and 34 under 35 U.S.C. §103(a) over *Kuntz* should be withdrawn.

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B. Rejection under 35 U.S.C. §103(a) over *Kuntz* in view of U.S. Patent No. 6,395,032 to *Gauchet*

In the Office Action, claims 2, 3, 14, and 19 are rejected as being allegedly unpatentable under 35 U.S.C. §103(a) over *Kuntz* in view of U.S. Patent No. 6,395,032 to *Gauchet* ("*Gauchet*"). This rejection is respectfully traversed.

Claims 2, 3, and 14 depend directly or indirectly from independent claim 1. Claim 19 has been canceled. Claim 1 as amended recites a resilient, compressible, biocompatible prosthesis formed from dissected human or animal tissue, an inorganic polymer, an organic polymer, or a combination thereof.

Gauchet is directed to an intervertebral disc prosthesis including two opposing plates, a flexible seal extending between the two plates for forming a closed chamber therebetween, and a liquid provided in the chamber (Abstract). The prosthesis of *Gauchet* is typically formed from titanium or titanium alloy plates with water in the chamber (col. 3, lines 42 and 44).

There is no motivation to combine the teachings of *Gauchet* with the teachings of *Kuntz*. As stated above, *Kuntz* is directed to a "substantially rigid" prosthesis (*Kuntz*, claim 1). Specifically, the prosthesis of *Kuntz* is formed from high density polyethylene, polymethylmethacrylate, stainless steel, or chrome cobalt alloys (col. 7, lines 53-55). There simply is nothing in *Kuntz* that would point to the fluid-filled prosthesis of *Gauchet*, and vice versa. Not surprisingly, the Office Action did not provide a motivation to combine the teachings of these very different references.

Furthermore, even if the references are combined, the combination of *Kuntz* and *Gauchet* fails to teach the resilient, compressible, biocompatible prosthesis formed from dissected human or animal tissue, an inorganic polymer, an organic polymer, or a combination thereof recited in claim 1. *Kuntz* recites various polymers, each of which is substantially rigid. *Gauchet* does not cure the deficiency of *Kuntz*, as *Gauchet* recites only titanium and titanium alloys. According to amended claim 1, any polymeric material used with the present invention must be both resilient and compressible.

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Given that there is no motivation to combine the teachings of *Kuntz* with the teachings of *Gauchet*, and that the combination fails to teach or suggest all elements of Applicant's claimed invention, a *prima facie* case of obviousness under 35 U.S.C. §103(a) has not been made with respect to amended claim 1 and its associated dependent claims 2, 13, and 14. As such, it is respectfully requested that the rejection be withdrawn.

C. Rejection under 35 U.S.C. §103(a) over *Kuntz* in view of U.S. Patent Application Serial No. US 2001/0039458A1 to *Boyer, II et al.*

In the Office Action, claims 8, 10, and 11 are rejected as being allegedly unpatentable under 35 U.S.C. §103(a) over *Kuntz* in view of U.S. Patent Application Serial No. US 2001/0039458A1 to *Boyer II et al.* ("*Boyer*"). This rejection is respectfully traversed.

Claims 8, 10, and 11 depend directly or indirectly from amended independent claim 1, which recites a resilient, compressible, biocompatible prosthesis formed from dissected human or animal tissue, an inorganic polymer, an organic polymer, or a combination thereof.

Neither *Kuntz* nor *Boyer* is directed to a prosthesis that is resilient and compressible. *Kuntz* is directed to a substantially rigid prosthesis. *Boyer* is directed to an implant formed from two or more bone fragments having a sheath and core configuration (p. 3, paragraph [0020]). Clearly, neither *Kuntz* nor *Boyer* contemplates Applicant's invention as recited in amended independent claim 1.

Given that neither *Kuntz* nor *Boyer*, alone or in combination, are sufficient to support a rejection of amended claim 1 under 35 U.S.C. §103(a), the rejection of dependent claims 8, 10, and 11 should be withdrawn.

D. Rejection under 35 U.S.C. §103(a) over *Kuntz* in view of U.S. Patent No. 6,187,043 to *Ledergerber*

In the Office Action, claims 26 and 33 are rejected as being allegedly unpatentable under 35 U.S.C. §103(a) over *Kuntz* in view of U.S. Patent No. 6,187,043 to *Ledergerber* ("*Ledergerber*"). This rejection is respectfully traversed.

As stated above, *Kuntz* is directed to a "substantially rigid" prosthesis (*Kuntz*, claim 1). *Ledergerber* is directed to various coverings for implants, primarily breast implants (col. 2, lines

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64-67 through col. 3, lines 1-4). The coverings of *Ledergerber* have various textures and configurations (col. 2, lines 64-67 through col. 3, lines 1-4). *Lederberger* is not directed to an implant itself.

There is no motivation to combine the teachings of *Kuntz* and *Ledergerber*. It is unclear what motivation the Examiner believes exists, since no motivation was provided in the Office Action. Further, even if the references are combined, the combination of *Kuntz* and *Ledergerber* does not teach or suggest all elements of Applicant's claimed invention. Specifically, the combination fails to teach or suggest a prosthesis *formed from* a length of biocompatible, compressible, resilient ribbon, as recited in amended claims 26 and 33.

Given that there is no motivation to combine the teachings of *Kuntz* with the teachings of *Ledergerber*, and that the combination fails to teach or suggest all elements of Applicant's claimed invention, a *prima facie* case of obviousness under 35 U.S.C. §103(a) has not been made. As such, it is respectfully submitted that the rejection of claims 26 and 33 be withdrawn.

E. New Claims

New claim 37, directed to a method of maintaining an intervertebral space between adjacent vertebrae, is believed to be allowable in that none of the cited references teach or suggest the method presented therein. New claims 38-45, which depend from claim 37, are also believed to be allowable because each claim adds an additional limitation or further defines the method recited in claim 37. Some such limitations include, for example, that the biocompatible material is compressible, that the material is a ribbon, or that the material has a semi-solid to solid consistency. Likewise, new claim 46 is believed to be allowable, as none of the cited references teach or suggest a sheet of biocompatible material for use in an intervertebral disc procedure as recited therein.

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V. CONCLUSION

The foregoing is submitted as a full and complete response to the Office Action mailed April 22, 2004 and is believed to place all claims in the application (claims 1-3, 6-8, 10, 11, 14, 15, 17, 18, 20, 24, 26-30, and 32-46) in condition for allowance. Such action is courteously solicited.

Applicant reserves the right to defend in later prosecution and in courts of law all claims herein on these and other grounds, including without limitation presenting challenges to any and all grounds for rejections stated in the Office Action.

If the Examiner believes that there are any issues that can be resolved by telephone conference, or if there are any informalities that may be addressed by an Examiner's amendment, please contact the undersigned at (404) 962-7523.

Respectfully submitted,

Date: 7/22/04

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